



Original research

Time Trends in Patient Characteristics and In-Hospital Adverse Events for Primary Total Knee Arthroplasty in the United States: 2010-2017

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ABSTRACT

Background: Perioperative care for total knee arthroplasty (TKA) has improved over time. We present an analysis of inpatient safety after TKA.

Methods: 14,057 primary TKAs captured by the Medicare Patient Safety Monitoring System between 2010 and 2017 were retrospectively reviewed. We calculated changes in demographics, comorbidities, and adverse events (AEs) over time. Risk factors for AEs were also assessed.

Results: Between 2010 and 2017, there was an increased prevalence of obesity (35.1% to 57.6%), tobacco smoking (12.5% to 17.8%), and renal disease (5.2% to 8.9%). There were reductions in coronary artery disease (17.3% to 13.4%) and chronic warfarin use (6.7% to 3.1%). Inpatient AEs decreased from 4.9% to 2.5%, ($P < .01$), primarily driven by reductions in anticoagulant-associated AEs, including major bleeding and hematomas (from 2.8% to 1.0%, $P < .001$), catheter-associated urinary tract infections (1.1% to 0.2%, $P < .001$), pressure ulcers (0.8% to 0.2%, $P < .001$), and venous thromboembolism (0.3% to 0.1%, $P = .04$). The adjusted annual decline in the risk of developing any in-hospital AE was 14% (95% confidence interval [CI] 10%–17%). Factors associated with developing an AE were advanced age (odds ratio [OR] = 1.01, 95% CI 1.00–1.01), male sex (OR = 1.21, 95% CI 1.02–1.44), coronary artery disease (OR = 1.35, 95% CI 1.07–1.70), heart failure (OR = 1.70, 95% CI 1.20–2.41), and renal disease (OR = 1.71, 95% CI 1.23–2.37).

Conclusions: Despite increasing prevalence of obesity, tobacco smoking, and renal disease, inpatient AEs after primary TKA have decreased over the past several years. This improvement is despite the increasing complexity of the inpatient TKA population over time.

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Introduction

Total knee arthroplasty (TKA) is one of the most commonly performed and successful surgical procedures in the United States [1]. Over the past decade, the growing demand for TKA has been met with improved patient optimization, minimally invasive surgical approaches, and efficient perioperative care pathways [2,3]. These refinements have been associated with reduced recovery times and overall costs of care [4]. As short hospital stays for TKA become more common [5–7], there is a greater need to monitor the longitudinal trends in safety with an emphasis on preoperative risk stratification.

Amid the advances in the perioperative management of patients undergoing TKA over the past few years, it remains unclear how the rates of in-hospital adverse events (AEs) have evolved during this time. In addition, as efforts to maximize patient safety continue to be a top priority, surgeons need to be able to accurately assess and mitigate patients' risks for developing postoperative complications. Risk stratification is essential to guide preoperative optimization, patient counseling, monitoring for AEs, and clinical decision-making.

The objective of this study was to report on the temporal trends in comorbidity profiles, rates of inpatient AEs, and risk factors for those AEs in a recent national sample of patients undergoing primary TKA at a hospital setting.

Material and methods

The institutional review board was waived based on the de-identified nature of the data. The Medicare Patient Safety Monitoring System (MPSMS), which includes only hospital stays and is detailed in previous publications [8–13], was queried for all patients who underwent primary, elective TKA from 2010 to 2017. The MPSMS is derived from chart abstraction; hence, compared to large administrative database analyses, identification of AEs is more sophisticated, includes more clinical details, and is potentially less prone to errors. Medical record abstraction was conducted by the Centers for Medicare and Medicaid Services' (CMS) Clinical Data Abstraction Center. Medical records in the MPSMS are randomly selected from the CMS "validation sample" for process-of-care measures required for the Hospital Inpatient Quality Reporting Program. Randomly selected hospitals contributed approximately equal numbers of randomly selected medical records to the MPSMS, regardless of their size. This sampling method is used to represent common in-hospital AEs at the national level.

Patient demographic factors that were assessed included age, sex, race (white, black, other), documentation of obesity, and tobacco smoking within 1 year of the surgery. In addition, a number of comorbidities including congestive heart failure (CHF), coronary artery disease (CAD), renal disease, cerebrovascular disease, chronic obstructive pulmonary disease, history of cancer, diabetes, and warfarin use in the week before admission were assessed.

The primary analyses were the temporal trends in patient characteristics and rates of in-hospital AEs over the study period. A complete list of postoperative AEs captured by the MPSMS database is provided in the Appendix A. A secondary outcome was to identify risk factors associated with the development of AEs.

A descriptive analysis to compare temporal differences in patient characteristics and in-hospital AEs was performed using the Mantel-Haenszel χ^2 test for categorical variables and the Kruskal-Wallis test for continuous variables. Linear mixed effects models were fitted with a logit link function to evaluate the temporal trends, adjusting for patient characteristics described previously. An ordinal time variable, ranging from 0 to 7, corresponding to years 2010 (time = 0) to 2017 (time = 7), was included in the models to represent the annual trend in AE rates. The models were also fitted with state-specific random intercepts to account for within-state and between-state variations. Analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC). The study followed the guidelines for cohort studies, described in the Strengthening of Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies [14].

Results

There were 14,057 patients included in the study. The mean (standard deviation) age was 65.7 (10.0), 37.5% were male, and 55.9% were older than 65 years. The mean annual patient sample

size was 1757 patients. Over the study period, there was a significant increase in the prevalence of obesity (35.17% to 57.6%, $P < .001$), tobacco smoking (12.5% to 17.8%, $P < .001$), and renal disease (5.2% to 8.9%, $P < .001$). This was accompanied by a significant decrease in the rates of CAD (17.3% to 13.4%, $P < .001$) and warfarin use during the week before surgery (6.7% to 3.1%, $P < .001$). Table 1 summarizes the demographic and comorbidity profiles of the study sample.

The percentage of patients experiencing in-hospital AEs decreased from 2010 to 2017 (4.9% to 2.5%, $P < .001$). Specifically, there were significant reductions in catheter-associated urinary tract infections (CAUTIs) (1.1% to 0.1%, $P < .001$), pressure ulcers (0.8% to 0.2%, $P < .001$), major bleeding or hematomas (2.8% to 1.0%, $P < .001$), and venous thromboembolism (VTE) (0.3% to 0.1%, $P = .035$). There were also significant reductions in drug-related AEs, including those related to low-molecular-weight heparin and factor Xa inhibitors (1.7% to 0.1%, $P < .001$), warfarin (0.8% to 0.1%, $P < .01$), and hypoglycemic agents (1.0% to 0.1%, $P < .001$). Collectively, AEs related to anticoagulants and major bleeding/hematomas showed the greatest decline (Fig. 1). There were no changes in the rates of inpatient falls, pneumonia, wound dehiscence, nonmajor hematoma, cardiovascular or cardiac events, deep infection, or mortality. Table 2 summarizes the annual rates of inpatient AEs. The adjusted annual decline in the risk of developing an AE was 14% (95% CI 10% to 17%).

Mixed models identified five patient factors that were associated with developing any inpatient AEs (Fig. 2): age (OR = 1.01, 95% CI 1.00–1.01 for each year of increased age), male sex (OR = 1.21, 95% CI 1.02–1.44), CAD (OR = 1.35, 95% CI 1.07–1.70), CHF (OR = 1.85, 95% CI 1.70 (1.20–2.41), and renal disease (OR = 1.71, 95% CI 1.23–2.37). Figure 2 presents a forest plot of the risk factors for developing a postoperative inpatient AE based on the mixed model.

Discussion

In this study, we used a nationwide, chart-abstracted patient safety monitoring database to examine the trends in comorbidities profiles and in-hospital AEs after primary TKA. We found significant upward trends in the rates of obesity, tobacco smoking, and renal disease but lower rates of CAD and warfarin use. Because MPSMS captures only the course of care during hospitalization, an increase in the prevalence of some comorbidities in our patient population could be related to the increasing tendency for TKA to be performed on an ambulatory basis, leaving the higher risk patients to more likely be included. There was a persistent decrease in the observed incidence of in-hospital AEs (a relative 14% per year), which was mainly due to reductions in major bleeding/hematoma, VTEs, pressure ulcers, CAUTIs, and adverse drug events related to hypoglycemics and anticoagulants. Advanced age, male sex, history of CAD, CHF, and renal disease were associated with in-hospital AEs.

Our study updates previous reports on the incidence of inpatient AEs after primary TKA. In a retrospective review of the MPSMS database between 2002 and 2004, Huddleston et al. [15] reported that the rates of major bleeding/hematoma, CAUTI, and VTE were 1.7%, 2.4%, and 1.1%, respectively. Ten years since that study, we found that the rates of those complications have decreased further, especially for CAUTI and VTE. In a more recent retrospective review using the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP), between 2006 and 2016, Sarpong et al. [16] found the rates of deep vein thrombosis and CAUTI to be 0.79% and 0.74%, respectively. The decline in CAUTIs is likely due to orthopedic surgeons increasingly abandoning the practice of routine indwelling catheters and widespread guidelines regarding appropriate use of urinary catheters [17,18]. The decline in the rates of major bleeding and hematoma is likely multifactorial. Since 2013, there has been widespread use of tranexamic acid

Table 1
Baseline characteristics of the study sample from 2010 to 2017.

Year	2010	2011	2012	2013	2014	2015	2016	2017	P value
N	2133	2545	2145	1247	1520	969	2159	1339	—
Age (y)	65.72 ± 10.46	65.68 ± 10.22	65.90 ± 9.82	65.45 ± 10.07	65.38 ± 9.62	65.42 ± 9.73	65.71 ± 9.92	65.81 ± 9.61	.6612
Sex									.1235
Male	777 (36%)	948 (37%)	798 (37%)	465 (37%)	562 (37%)	376 (39%)	840 (39%)	505 (38%)	
Female	1356 (64%)	1597 (63%)	1347 (63%)	782 (63%)	958 (63%)	593 (61%)	1319 (61%)	834 (62%)	
Insurance type									.3296
Medicare	1170 (55%)	1310 (51%)	1166 (54%)	659 (53%)	750 (49%)	506 (52%)	1128 (52%)	722 (54%)	
Other	963 (45%)	1235 (49%)	979 (46%)	588 (47%)	770 (51%)	463 (48%)	1031 (48%)	617 (46%)	
Race									.6845
White	1837 (86%)	2201 (87%)	1892 (88%)	1086 (87%)	1314 (86.5%)	841 (87%)	1870 (87%)	1154 (86%)	
Black	167 (8%)	187 (7%)	146 (7%)	98 (8%)	114 (7.5%)	74 (8%)	169 (8%)	105 (8%)	
Other	129 (6%)	157 (6%)	107 (5%)	63 (5%)	92 (6%)	54 (5%)	120 (5%)	80 (6%)	
Diabetes	566 (26.5%)	638 (25.1%)	559 (26.1%)	308 (24.7%)	347 (22.8%)	235 (24.2%)	544 (25.2%)	351 (26.2%)	.4169
Obesity	748 (35.07%)	1023 (40.2%)	938 (43.7%)	608 (48.8%)	762 (50.1%)	549 (56.7%)	1239 (57.4%)	772 (57.6%)	<.0001
Current smoker	267 (12.5%)	323 (12.7%)	282 (13.1%)	187 (15%)	230 (15.1%)	152 (15.7%)	374 (17.3%)	239 (17.8%)	<.0001
Cancer	261 (12.2%)	287 (11.3%)	251 (11.7%)	145 (11.6%)	181 (11.9%)	119 (12.3%)	286 (13.2%)	168 (12.5%)	.1208
CVD	127 (5.9%)	145 (5.7%)	118 (5.5%)	78 (6.3%)	81 (5.3%)	60 (6.2%)	122 (5.6%)	82 (6.1%)	.8758
CHF/pulmonary edema	109 (5.1%)	121 (4.7%)	97 (4.5%)	54 (4.3%)	58 (3.8%)	40 (4.1%)	104 (4.8%)	62 (4.6%)	.4499
COPD	192 (9%)	262 (10.3%)	181 (8.4%)	103 (8.3%)	13 (8.6%)	104 (10.7%)	189 (8.7%)	121 (9%)	.5985
CAD	370 (17.3%)	449 (17.6%)	365 (17%)	193 (15.5%)	202 (13.3%)	138 (14.2%)	292 (13.5%)	180 (13.4%)	<.0001
Renal disease	112 (5.2%)	151 (5.9%)	146 (6.8%)	84 (6.7%)	96 (6.3%)	75 (7.7%)	164 (7.6%)	119 (8.9%)	<.0001
Warfarin in week before surgery	142 (6.7%)	136 (5.3%)	154 (7.2%)	76 (6.1%)	63 (4.1%)	40 (4.1%)	85 (3.9%)	42 (3.1%)	<.0001

COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease.

administered intraoperatively, which has been shown to reduce blood loss and transfusion risk for TKA [19]. In addition, the past few years have witnessed a greater shift toward the use of aspirin for deep vein thrombosis prophylaxis as an alternative to warfarin and heparin-based anticoagulants [20–22]. In our study, in 2010, 95.1% of patients received warfarin, low-molecular-weight heparin, or a factor Xa inhibitor, while in 2017, only 40.5% of patients received these agents. This factor likely played a role in the marked decrease in the rate of AEs attributed to nonaspirin anticoagulants. MPSMS does not abstract aspirin use, so we were unable to detect

the rates of bleeding events specifically related to aspirin; nonetheless, the overall rate of major bleeding/hematomas, whether or not associated with a specific agent, declined significantly.

Although we observed relatively low rates of in-hospital mortality ranging from 0.1% to 0.3%, these rates have remained stagnant during our study period and even when compared to older reports. In a retrospective review of the MPSMS database between 2002 and 2004, Huddleston et al. [15] found a 0.3% rate of inpatient mortality among patients undergoing primary TKA. In a systematic review of the literature, Berstock et al. [23] estimated the 30- and 90-day

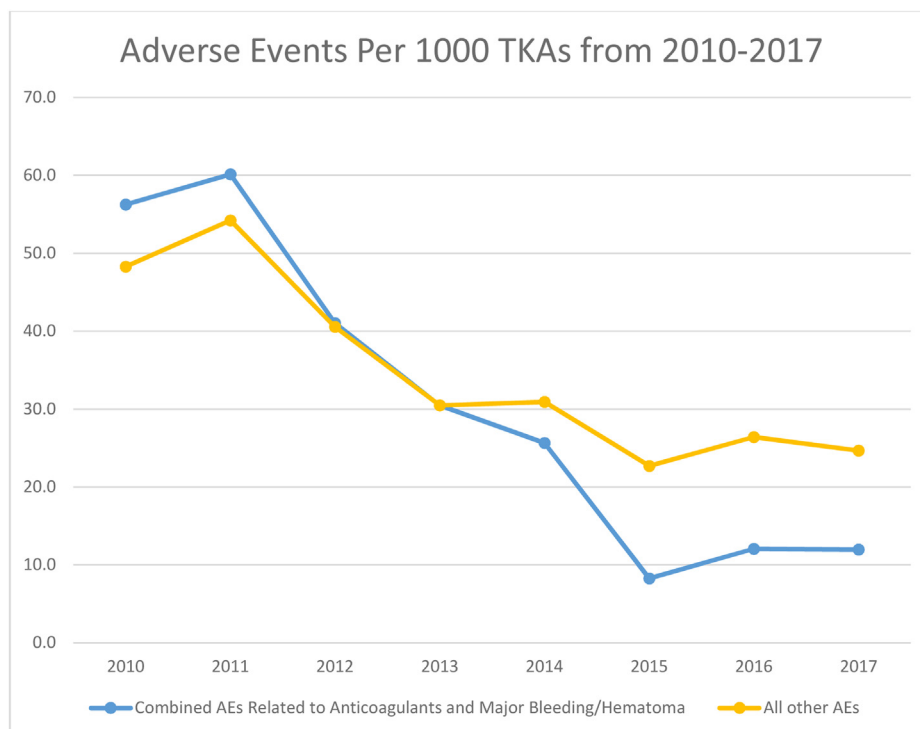


Figure 1. Temporal trends in adverse events related to anticoagulants (other than aspirin) and major bleeding/hematoma for primary total knee arthroplasty.

Table 2
Rates of in-hospital adverse events from 2010 to 2017.

Year	2010	2011	2012	2013	2014	2015	2016	2017	P value
Total patients, N	2133	2545	2145	1247	1520	969	2159	1339	
	N (%)								
Any adverse event (AE)	105 (4.92)	121 (4.75)	78 (3.64)	28 (2.25)	40 (2.63)	20 (2.06)	44 (2.04)	33 (2.46)	<.0001
Mortality	1 (0.05)	7 (0.28)	1 (0.05)	2 (0.16)	1 (0.07)	0 (0.00)	6 (0.28)	2 (0.15)	.5269
Return to operating room	3 (0.14)	3 (0.12)	2 (0.09)	0 (0.00)	0 (0.00)	1 (0.10)	2 (0.09)	2 (0.15)	.7649
AEs associated with hypoglycemic agents	21 (0.98)	18 (0.71)	9 (0.42)	2 (0.16)	5 (0.33)	4 (0.41)	5 (0.23)	1 (0.07)	<.0001
AEs associated with intravenous heparin	1 (0.05)	1 (0.04)	2 (0.09)	0 (0.00)	1 (0.07)	0 (0.00)	0 (0.00)	0 (0.00)	.2096
AEs associated with low-molecular-weight heparin and factor Xa inhibitor	36 (1.69)	57 (2.24)	32 (1.49)	15 (1.20)	13 (0.86)	2 (0.21)	3 (0.14)	1 (0.07)	<.0001
AEs associated with warfarin	18 (0.84)	27 (1.06)	13 (0.61)	8 (0.64)	2 (0.13)	0 (0.00)	1 (0.05)	0 (0.00)	<.0001
Catheter-associated urinary tract infections	23 (1.08)	29 (1.14)	15 (0.7)	9 (0.72)	6 (0.39)	4 (0.41)	2 (0.09)	2 (0.15)	<.0001
Pressure ulcers	18 (0.84)	23 (0.90)	19 (0.89)	6 (0.48)	4 (0.26)	2 (0.21)	3 (0.14)	2 (0.15)	<.0001
Falls	17 (0.80)	29 (1.14)	21 (0.98)	15 (1.20)	19 (1.25)	3 (0.31)	17 (0.79)	5 (0.37)	.0628
Cardiac events	2 (0.09)	6 (0.24)	4 (0.19)	1 (0.08)	3 (0.20)	0 (0.00)	4 (0.19)	4 (0.30)	.5915
Pneumonia	10 (0.47)	11 (0.43)	8 (0.37)	1 (0.08)	7 (0.46)	1 (0.10)	5 (0.23)	3 (0.22)	.0644
Venous thromboembolic events	6 (0.28)	9 (0.35)	10 (0.47)	4 (0.32)	3 (0.20)	2 (0.21)	3 (0.14)	1 (0.07)	.0351
Deep infection	1 (0.05)	1 (0.04)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	2 (0.09)	0 (0.00)	.9104
Wound dehiscence	1 (0.05)	3 (0.12)	1 (0.05)	0 (0.00)	1 (0.07)	0 (0.00)	1 (0.05)	1 (0.07)	.6577
Hematoma	6 (0.28)	4 (0.16)	6 (0.28)	1 (0.08)	4 (0.26)	1 (0.1)	3 (0.14)	2 (0.15)	.3178
Major bleeding/hematoma	59 (2.77)	64 (2.51)	35 (1.63)	14 (1.12)	19 (1.25)	5 (0.52)	19 (0.88)	13 (0.97)	<.0001
Cardiovascular AEs	6 (0.28)	7 (0.28)	7 (0.33)	2 (0.16)	0 (0.00)	1 (0.10)	3 (0.14)	4 (0.30)	.2268
Revision surgery during index hospitalization	0 (0.00)	1 (0.04)	0 (0.00)	0 (0.00)	1 (0.07)	6 (0.62)	7 (0.32)	7 (0.52)	<.0001

mortality after TKA at 0.2% and 0.4%, respectively, with cardiovascular complications such as myocardial infarction being the primary cause for mortality.

It should come as no surprise that our multivariate analyses identified preoperative CAD as an independent risk factor for AEs along with advanced age, male sex, renal disease, and CHF. These findings are consistent with some previous reports. In a recent retrospective review using the ACS-NSQIP database, Robinson et al. [24] found that male gender was associated with higher risk for sepsis and cardiovascular complications. In another ACS-NSQIP study, Curtis et al. [25] demonstrated increased risk for wound dehiscence and myocardial infarction in patients with heart failure.

One of the interesting findings of this study is the reduction in overall rates of AEs despite the increasing prevalence of obesity, tobacco smoking, and renal disease in our sample and the abundant evidence demonstrating the negative postsurgical impact of those factors [26,27]. A plausible explanation that may be contributing to the overall reduction in AEs is the increased awareness and screening for those risk factors in the preoperative period. Value-based incentive payment programs measuring risk-standardized complication rates for elective primary THA and TKA procedures, such as the CMS' Hospital Value-Based Purchasing program, may further incentivize documentation of certain risk factors. Furthermore, changes in specific processes of care may have played a role

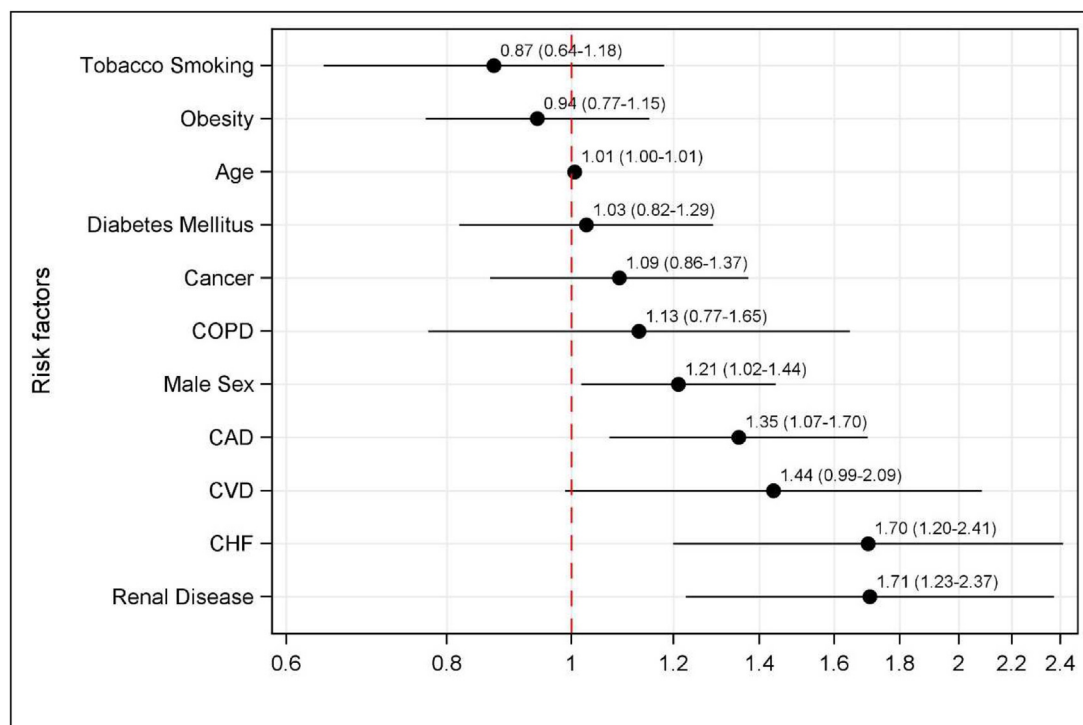


Figure 2. Risk factors associated with developing a postoperative in-hospital adverse event. COPD, chronic obstructive pulmonary disease; CVD, cerebrovascular disease.

for some types of AEs, for example, declining usage of perioperative bladder catheterization might contribute to decreasing CAUTI rates. Preoperative optimization has received heightened attention in the arthroplasty community during the study period. Springer [27] and Thomsen et al. [28] showed that preoperative smoking cessation resulted in lower risk of postsurgical AEs and need for revision surgery. Similarly, more patients are now undergoing weight loss programs including bariatric surgery before joint arthroplasty, potentially optimizing associated comorbidities and leading to improved outcomes [29,30]. Growing efforts by orthopedic surgeons to address modifiable risk factors before surgery may, therefore, be helpful in mitigating their detrimental effects.

This study should be interpreted in the context of some limitations. First, given the retrospective methodology, we can only measure AEs that are detected and documented. Second, MPSMS does not collect all potential AEs. Furthermore, the declining length of stay (from a mean of 3.4 ± 1.5 days in 2010 to 2.4 ± 1.2 days in 2017) during the period of our study could have reduced the chance of detecting late AEs, such as VTE, wound dehiscence, or CAUTI. However, our findings corroborate recent reports of THA and TKA 90-day complication rates calculated using administrative claims data, supporting the validity of our study results [31]. Third, the lack of significant trends for certain AEs and mortality may be due to insufficient power to detect an association with these very rare AEs. Fourth, no conclusions can be drawn regarding complications occurring after hospital discharge. Fifth, it is possible that the decreased in-hospital complication rates could be related because of improved documentation of chronic conditions present on admission. Finally, as a primarily safety monitoring database, it was not possible to pinpoint the specific reasons for the observed decline in complication rates.

Conclusions

The safety of inpatient TKA has continued to improve over the past decade despite worsening trends in the prevalence of obesity, tobacco smoking, and renal disease in our sample. Elderly male patients, especially those with CAD, chronic heart failure, and/or renal disease appear to be at the highest risk for experiencing in-hospital AEs.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.artd.2014.12.004>.

Conflicts of interest

M.J.H. is in the editorial or governing board of *Journal of Bone and Joint Surgery* and *Arthroplasty Today* and is a board member for American Orthopaedic Association. L.G.S. receives \$5000 for consultancy on NIH grant on knee OA (PI, E. Losina) through Brigham & Women's Hospital, receives salary support from Centers for Medicare and Medicaid services through contract to YNHHS to develop, maintain, and implement quality measures for federal payment programs, and is a board member for Quality Measures Subcommittee Chair for American College of Rheumatology.

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